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EXAMINER

JANG, CHRISTIAN YONGKYUN

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,004	Applicant(s) GHIGINI, FRANCESCA	
	Examiner CHRISTIAN JANG	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed on December 10th, 2009. Claims 11-30 are pending in the instant application. Amendments to claims 11, 17, and 27 are acknowledged by the examiner.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pickering et al. (USP #6,168,567) in view of Ogura et al. (US 2002/0120199).

4. As to claims 11, 14, and 17, Pickering teaches a device and corresponding method for detecting arterial pressure (Abs). The device comprises a cuff with inflatable chamber for placing around the arm of a patient (12), means for introducing air into cuff (14), decompression means (16), means for detecting arterial pressure by a technique that provides for the intervention of an operator to detect the sphygmic pulses using a stethoscope (col. 3 lines 53-61) and make a subjective judgment of said pulses (18), associated by the operator to systolic and diastolic pressures (col. 3 lines 53-61). Pickering fails to teach that the sphygmic pulses are detected and stored in chart form and that the chart shows all the pulses detected by the means. However, Ogura teaches a blood pressure measuring apparatus which detects and stores measured pulses in a waveform (i.e. chart form) (86). Although Pickering does not teach that the

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blood pressure measurement is stored or displayed as a waveform, the method of detection allows for measurement of the entire pulse in a waveform. The ability to store the entire waveform would allow for the operator to determine additional parameters and patterns associated with the blood pressure measurement. As such, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the blood pressure measurement device of Pickering with the BP measurement device which detects and stores BP waveforms as taught by Ogura to enable the operator to further obtain diagnostically relevant values and parameters.

5. As to claims 12 and 18, Pickering teaches a decompression means comprising a valve for providing constant and time-controlled decompression (col. 3 line 62 to col. 4 line 8).

6. As to claim 13, Pickering teaches a discharge means adapted to completely and instantaneously discharge the inflatable chamber of said cuff (col. 4 lines 2-5).

7. As to claim 15, Ogura teaches a display adapted to display detected levels of pressure and sphygmic intensity ([0151]).

8. As to claim 16, Pickering teaches a button adapted to be pressed by the operator when the operator detects sphygmic pulses that correspond to systolic or diastolic pressures (18).

9. As to claim 19, Pickering teaches a step for storing the pulse information for further analysis (col. 6 line 10-15).

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10. As to claim 20, Pickering teaches step of pressing a button by the operator when the operator detects sphygmie pulses that correspond to systolic or diastolic pressures to be marked on a digital scale of said device (18).

11. Claims 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shirasaki et al. (USP #5,522,395) in view of Park et al. (US 2002/0183631) and further in view of Sjonell (USP #5,042,496).

12. As to claim 21, Shirasaki teaches a device for detecting arterial pressure comprising a cuff (1), means for inflating said cuff (2), decompression means (3), memory means (8) to detect and store the sphygmie pulses. The device allows for the identification of pulses (Fig. 8) and inherently provides for intervention of an operator to detect the sphygmie pulses and to make a subjective judgment (by viewing the graph and coming to a conclusion). Shirasaki fails to teach the storage of data in chart form. However, Park teaches a device for detecting the pulse wave of the user and storing the measured pulse wave information (Abs). Since graphs are derived from the pulse wave data by applicant's own admission ([0031]), this would be equivalent to the storage of data in chart form. As such, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the arterial pressure measurement device of Shirasaki with the pulse wave storage means taught by Park to enable the user to store the entirety of the measurement data for further analysis. The combined teachings of Shirasaki and Park fail to teach a cuff provided with a printed scale that indicates, when the cuff is applied to the patient, the circumference of the arm of the patient. Sjonell

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teaches a cuff with a tape measure mounted on the cuff so as to enable the measurement of arm circumference when placed on the arm in a conventional manner so as to use the arm circumference measurement to correct the blood pressure measurement (col. 2, line 35 to col. 3, line 15). As such, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the arterial pressure measurement device of Shirasaki incorporating the pulse wave storage means taught by Park with the cuff incorporating a printed scale similar to that of Sjonell in order to allow measurement of the arm circumference to allow for correction action on the blood pressure measurement.

13. As to claim 22, Shirasaki teaches a decompression means comprising a valve for providing constant and time-controlled decompression (3).

14. As to claim 23, Shirasaki teaches a decompression means comprising a valve for instantaneous discharge of the chamber (3).

15. As to claim 24, Park teaches that the detecting and storing means are connected to data storage means (50).

16. As to claim 25, Park teaches a display adapted to display detected levels of pressure and levels of sphygmie intensity of the pulsations (40).

17. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shirasaki et al. (USP #5,522,395), Park et al. (US 2002/0183631), and Sjonell (USP #5,042,496) as applied to claim 21 above, and further in view of Barker (USP #5,201,320).

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18. As to claim 26, the combined teaching of Shirasaki, Park, and Sjonell do not disclose a button to be pressed by an operator when the operator detects pulses corresponding to systolic or diastolic pressures. Barker teaches buttons or switches 32 and 34 (col. 4, lines 39-43) for the purpose of marking off the pressure readings of systolic and diastolic pressures. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the arterial pressure measurement device of Shirasaki incorporating the pulse wave storage means taught by Park and the cuff incorporating a printed scale taught by Sjonell with the button apparatus taught by Barker in order to simplify operation of the device, to allow the operator to concentrate on determining only the points of systolic or diastolic pressure, without needing to account for the actual pressure readings themselves.

19. Claims 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pickering et al. (USP #6,168,567) in view of Ogura et al. (US 2002/0120199), and further in view of Sjonell (USP #5,042,496).

20. As to claim 27, the combined teachings of Pickering and Ogura disclose the invention substantially as claimed. The combined teachings of Pickering and Ogura fail to teach the identifying of the value of the circumferences of the arm by reading a scale printed on the cuff. Sjonell teaches a cuff with a tape measure mounted on the cuff so as to enable the measurement of arm circumference when placed on the arm in a conventional manner so as to use the arm circumference measurement to correct the blood pressure measurement (col. 2, line 35 to col. 3, line 15). As such, it would have

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been obvious to one of ordinary skill in the art at the time of the invention to modify the arterial pressure measurement device of Pickering incorporating the BP measurement device which detects and stores BP waveforms taught by Ogura with the cuff incorporating a printed scale similar to that of Sjonell in order to allow measurement of the arm circumference to allow for correction action on the blood pressure measurement.

21. As to claim 28, Pickering teaches a decompression means comprising a valve for providing constant and time-controlled decompression (col. 3 line 62 to col. 4 line 8).

22. As to claim 29, Pickering teaches a step for storing the pulse information for further analysis (col. 6 line 10-15).

23. As to claim 30, Pickering teaches step of pressing a button by the operator when the operator detects sphygmie pulses that correspond to systolic or diastolic pressures to be marked on a digital scale of said device (18).

Response to Arguments

24. Applicant's arguments with respect to claims 11-20 and 27-30 have been considered but are moot in view of the new ground(s) of rejection.

25. Applicant's arguments filed December 10th, 2009 regarding the rejection of claims 21-25 under 35 USC 103(a) as being unpatentable over Shirasaki et al, in view of Park et al. and further in of Sjonell have been fully considered but they are not persuasive.

26. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections

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are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

27. In response to applicant's argument that Shirasaki does not disclose a device in which the pulses are detected by a combination of an electronic unit and of a technique to detect the systolic and diastolic pressure, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN JANG whose telephone number is (571)270-3820. The examiner can normally be reached on Mon-Fri (9-6:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

CJ
/C. J./
Examiner, Art Unit 3735
2/23/10